



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0793]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Recall Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements for medical device recall authority.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Device Recall Authority--21 CFR 810 (OMB Control Number 0910-0432)--Extension

This collection of information implements section 518(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360h(e)) and part 810 (21 CFR part 810), medical device recall authority provisions. Section 518(e) of the FD&C Act provides FDA with the authority to issue an order requiring an appropriate person, including manufacturers, importers, distributors, and retailers of a device, if FDA finds that there is reasonable probability that the device intended for human use would cause serious adverse health consequences or death, to: (1) Immediately cease distribution of such device; (2) immediately notify health professionals and device-user facilities of the order; and (3) instruct such professionals and facilities to cease use of such device.

Further, the provisions under section 518(e) of the FD&C Act set out the following three-step procedure for issuance of a mandatory device recall order:

- If there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, FDA may issue a cease distribution and notification order requiring the appropriate person to immediately:
 - Cease distribution of the device,
 - notify health professionals and device user facilities of the order, and
 - instruct those professionals and facilities to cease use of the device;
- FDA will provide the person named in the cease distribution and notification order with the opportunity for an informal hearing on whether the order should be modified, vacated, or amended to require a mandatory recall of the device; and
- after providing the opportunity for an informal hearing, FDA may issue a mandatory recall order if the Agency determines that such an order is necessary.

The information collected under the recall authority provisions will be used by FDA to do the following: (1) Ensure that all devices entering the market are safe and effective; (2) accurately and immediately detect serious problems with medical devices; and (3) remove dangerous and defective devices from the market.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Collection Activity--21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Collections Specified in the Order--810.10(d)	2	1	2	8	16
Request for Regulatory Hearing--810.11(a)	1	1	1	8	8
Written Request for Review--810.12(a-b)	1	1	1	8	8
Mandatory Recall Strategy--810.14	2	1	2	16	32
Periodic Status Reports--810.16(a-b)	2	12	24	40	960
Termination Request--810.17(a)	2	1	2	8	16
Total Hours					1,040

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden¹

Collection Activity--21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Documentation of Notifications to Recipients--810.15(b)	2	1	1	8	8

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 3.--Estimated Annual Third-Party Disclosure Burden¹

Collection Activity--21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Notification to Recipients--810.15(a)-(c)	2	1	2	12	24
Notification to Recipients; Followup--810.15(d)	2	1	2	4	8
Notification of Consignees by Recipients--810.15(e)	10	1	10	1	10
Total					42

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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